

#18

Substitute for form 1449A/PTO  
**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
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Sheet 1 of 6

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**Application Number** 09/689,136  
**Filing Date** October 12, 2000  
**First Named Inventor** Engelhardt, John  
**Group Art Unit** 1641  
**Examiner Name** Sullivan, Daniel

Attorney Docket No: 875.032US1

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## US PATENT DOCUMENTS

Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	Filing Date If Appropriate
DS	US-5,604,090	02/18/1997	Alexander, Ian E., et al.	435	5	06/06/1994
DS	US-5,691,176	11/25/1997	Lebkowski, J. S., et al.	435	172.3	06/02/1995
DS	US-5,834,182	11/10/1998	Alexander, Ian E., et al.	435	5	02/25/1997
DS	US-6,083,702	07/04/2000	Mitchell, L. G., et al.	435	6	08/13/1998
DS	US-6,200,560	03/13/2001	Couto, L. B., et al.	424	93.2	12/22/1999

Already of record (#10)

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Foreign Document No	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	T <sup>2</sup>
DS	WO-94/13788 ✓	12/04/1992	Coruzzi, Laura A., et al.	C12N	7/01	
DS	WO-95/07351 ✓	09/10/1993	Jarrell, Kevin A.	C12N	15/10	
DS	WO-97/22250 ✓	12/13/1996	Mitchell, Lloyd G.	A01N	43/04	
DS	WO-98/09657 ✓	09/06/1996	Wilson, James M., et al.	A61K	48/00	

## OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
DS		"(S)-(+)-Camptothecin; 4-Ethyl-4-hydroxy-1H-pyrano[3', 4': 6,7] indolizino [1,2- b] quinoline-3, 14 (4H, 12H) dione", <u>Calbiochem</u> , Camptothecin, Camptotheca acuminata, (October 2, 2000), 1-2	
DS		"Adriamycin; 14-Hydroxydaunomycin, HCl", <u>Calbiochem</u> , Doxorubicin, Hydrochloride, Catalog Number 324380, (October 21, 1998), 1-2	
DS		"Aminoglycoside antibiotic. Inhibits myeloperoxidase-dependent oxidant cell injury", <u>Calbiochem</u> , Tobramycin, Free Base, Catalog Number 614005, (August 26, 1999), 1	
DS		"Cancer Research", <u>Contribution to Society</u> , <a href="http://www.bikaken.or.jp/mcrf_e/contribution">http://www.bikaken.or.jp/mcrf_e/contribution</a> , (December 4, 2000), 2 pages	
DS		"Carbobenzoxo-L-leucyl-L-leucinal", <u>Calbiochem</u> , MG-132, Catalog Number 474790, (October 15, 1999), 1-2	
DS		"Drugs for Selection of Genetic Markers Reagents for positive and negative selection of Genes involved in Nucleotide Metabolism", <u>Calbiochem</u> , (March 2002), 6 pages	
DS		"EPA; 20:5 w-3; 5,8, 11, 14, 17-Eicosapentaenoic Acid", <u>Calbiochem</u> , Eicosapentaenoic Acid, Catalog Number 324875, (December 7, 1998), 1-2	
DS		"Epoxomicin- a potent and selective proteasome inhibitor", <u>Affiniti Research Products Limited</u> , 2 pages	
DS		"LDP-341", <u>Millennium Pharmaceuticals</u> , <a href="http://www.biospace.com/ct/detail.cfm?ClinicalID=266404">http://www.biospace.com/ct/detail.cfm?ClinicalID=266404</a> , 1 page	✓
DS		"Mevinolin; MK-803", <u>Calbiochem</u> , Lovastatin, Catalog Number 438185, (June 29, 2001), 1-2	✓

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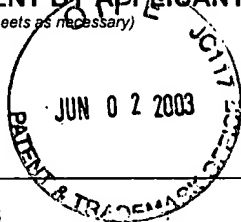
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DS		"MK-733", <u>Calbiochem</u> , Simvastatin, Catalog Number 567020, (October 25, 2001), 2	✓
DS		"Polymer Vectors Endosomal release and cytoplasmic delivery", <u>Endosomal Release</u> , <a href="http://web.bham.ac.uk/can4psd4/nonviral/endosome.html">http://web.bham.ac.uk/can4psd4/nonviral/endosome.html</a> , (June 3, 2001), 1	✓
DS		"Product Data Sheet", <u>Moravek Biochemicals, Inc.</u> , M-1535, Ritonavir, (July 12, 2001), 1 page	✓
DS		"Product Information", <u>Sigma</u> , Cyclosporin A, Sigma Product No. C3662, (October 28, 1996), 3 pages	✓
DS		"Product Information", <u>Sigma</u> , Bleomycin Sulfate, Sigma Prod. No. B5507, (November 25, 1996), 2 pages	✓
DS		"Proteasome Inhibitors", <u>Peptides International, Inc.</u> , (April 16, 2001), 1-2	✓
DS		"Tannic Acid, A.C.S. reagent", <u>Sigma</u> , <a href="http://www.sigma-aldrich.com/sacatalog.nsf/productlookup/Aldrich403040?OpenDocument">www.sigma-aldrich.com/sacatalog.nsf/productlookup/Aldrich403040?OpenDocument</a> , 1 page	✓
DS		ADAMS, JULIAN, et al., "Novel Inhibitors of the Proteasome and Their Therapeutic Use in Inflammation", <u>Annual Reports in Medicinal Chemistry</u> , Academic Press, Inc., (1996), 279-288	✓
DS		ANDRE, PATRICE, et al., "An inhibitor of HIV-1 protease modulates proteasome activity, antigen presentation, and T cell responses", <u>Proc. National Academy of Science USA</u> , vol. 95, (October 1998), 13120-13124	✓
DS		BANERJEE, D., et al., "The treatment of respiratory pseudomonas infection in cystic fibrosis: What drug and which way?", <u>Drugs</u> , 60(5), abstract, (November 2000), 1 page	✓
DS		BIES, J., et al., "Oncogenic activation of c-Myb by Carboxyl-Terminal truncation leads to Decreased Proteolysis by the Ubiquitin-26S proteasome pathway", <u>Oncogene</u> , vol. 14, no. 2, Abstract, (January 16, 1997), 1 page	✓
DS		BOKKALA, SHAILA, et al., "Angiotensin II-induced Down-regulation of Inositol Trisphosphate Receptors in WB Rat Liver Epithelial Cells", <u>Journal of Biological Chemistry</u> , vol. 272, no. 19, (May 9, 1997), 12454-12461	✓
DS		BONACORSI, STEPHANE, et al., "Comparative In Vitro Activities of Meropenem, Imipenem, Temocillin, Piperacillin, and Ceftazidime in Combination with Tobramycin, Rifampin, or Ciprofloxacin against Burkholderia cepacia Isolates from Patients with Cystic Fibrosis", <u>Antimicrobial Agents and Chemotherapy</u> , vol. 43, no. 2, (February 1999), 213-217	✓
DS		BRAND, STEPHEN, et al., "Role of the Proteasome in Rat Indomethacin-Induced Gastropathy", <u>Gastroenterology</u> , vol. 116, no. 4, (1999), 865-873	✓
DS		BRAVO, LAURA, "Polyphenols: Chemistry, Dietary Sources, Metabolism and Nutritional Significance", <u>Nutrition Reviews</u> , vol. 56, no. 11, (November 1998), 317-333	✓
DS		BUGG, C., et al., "SRI6975 Increases Adenovirus Mediated Gene Transfer Through the Apical Surface of Polarized MDCK Cell Monolayers", <u>Cystic Fibrosis</u>	✓

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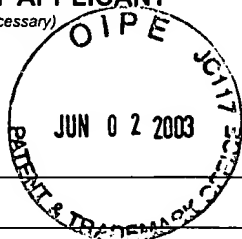
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Group Art Unit	1641
Examiner Name	Sullivan, Daniel

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		Foundation: 2000 North American CF Conference, (November 2000),1	
DS		CANTIN, ANDRE M., et al., "Aerosolized Prolastin Suppresses Bacterial Proliferation in a Model of Chronic Pseudomonas aeruginosa Lung Infection", <u>American Journal of Respiratory and Critical Care Medicine</u> , vol. 160, (1999),1130-1135	✓
DS		CHUNG, KING-THOM, et al., "Tannis and Human Health: A Review", <u>Critical Reviews in Food Science and Nutrition</u> , 38(6), (1998),421-464	✓
DS		DESAI, SHYAMAL, et al., "Ubiquitin-dependent Destruction of Topoisomerase I Is Stimulated by the Antitumor Drug Camptothecin", <u>Journal of Biological Chemistry</u> , (September 26, 1997),24159-24164	✓
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PC		FAYADAT, LAURENCE, et al., "Degradation of Human Thyroperoxidase in the Endoplasmic Reticulum Involves Two Different Pathways Depending on the Folding State of the Protein", <u>Journal of Biological Chemistry</u> , vol. 275, no. 21, (May 26, 2000),15948-15954	✓
DS		FENTEANY, GABRIEL, et al., "Lactacystin, Proteasome Function, and Cell Fate", <u>Journal of Biological Chemistry</u> , vol. 273, no. 15, (April 10, 1998),8545-8548	✓
DS		FIGUEIREDO-PEREIRA, MARIA, et al., "The Antitumor Drug Aclacinomycin A, Which Inhibits the Degradation of Ubiquitinated Proteins, Shows Selectivity for the Chymotrypsin-like Activity of the Bovine Pituitary 20 S Proteasome", <u>Journal of Biological Chemistry</u> , (July 12, 1996),16455-16459	✓
DS		GABIZON, ALBERTO, "Long-circulating liposomes for drug delivery in cancer therapy: a review of biodistribution studies in tumor-bearing animals", <u>Advanced Drug Delivery Reviews</u> , (1997),337-344	✓
DS		GABIZON, ALBERTO, et al., "Preclinical Studies with Doxorubicin Encapsulated in Polyethyleneglycol-Coated Liposomes", <u>Journal of Liposome Research</u> , 3(3), (1993),517-528	✓
DS		GARBER, KEN, "Taking Garbage In, Taking Cancer Out?", <u>Science</u> , vol. 295, (January 25, 2002),612-613	✓
DS		HASEGAWA, S., et al., "Microtubule involvement in the intracellular dynamics for gene transfection mediated by cationic liposomes", <u>Gene Therapy</u> , vol. 8, (2001),1669-1673	✓
DS		HONG, J., et al., "Identification of SRI6975, A Compound that Enhances Adenovirus-Mediated Gene Expression in Polarized Epithelial Cells", <u>Cystic Fibrosis Foundation: 2000 North American CF Conference</u> , (November 2000),1-2	✓
DS		HSU, A., et al., "Ritonavir. Clinical pharmacokinetics and interactions with other	✓

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		anti-HIV agents", <u>Clin Pharmacokinetics</u> , 35(6), abstract, (December 1998), 1 page	
AS		HUANG, L., et al., "Efficient lipofection with cisplatin-resistant human tumor cells", <u>Cancer Gene Therapy</u> , vol. 3, no. 2, (1996), 107-112	✓
AS		IQBAL, MOHAMED, et al., "Potent Inhibitors of Proteasome", <u>Journal of Medicinal Chemistry</u> , vol. 38, no. 13, (1995), 2276-2277	✓
AS		KIM, KYUNG BO, et al., "Proteasome Inhibition by the Natural Products Epoxomicin and Dihydroeponepymycin: Insights into Specificity and Potency", <u>Bioorganic &amp; Medicinal Chemistry Letters</u> , (1999), 3335-3340	✓
AS		LEE, SANG GOO, et al., "Enhancement of adenoviral transduction with polycationic liposomes in vivo", <u>Cancer Gene Therapy</u> , vol. 7, no. 10, (2000), 1329-1335	✓
AS		LEE, D. H., "Proteasome Inhibitors: Valuable New Tools For Cell Biologists", <u>Trends in Cell Biology</u> , 8, (October 1998), pp. 397-403	✓
AS		LEE, DO HEE, et al., "Selective Inhibitors of the Proteasome-dependent and Vacuolar Pathways of Protein Degradation in <i>Saccharomyces cerevisiae</i> ", <u>Journal of Biological Chemistry</u> , (November 1, 1996), 27280-27284	✓
AS		LEE, DO HEE, et al., "The Proteasome Inhibitors and Their Uses", <u>Proteasomes: The World of Regulatory Proteolysis</u> , (2000), 154-175	✓
AS		LU, WEI, et al., "HIV protease inhibitors restore impaired T-cell proliferative response in vivo and in vitro: a viral-suppression-independent mechanism", <u>Blood</u> , vol. 96, no. 1, (July 1, 2000), 250-258	✓
AS		LUO, HONGYU, et al., "A Proteasome Inhibitor Effectively Prevents Mouse Heart Allograft Rejection", <u>Transplantation</u> , vol. 72, no. 2, (July 27, 2001), 196-202	✓
AS		MASTROIANNI, CLAUDIO M., et al., "Ex Vivo and In Vitro Effect of Human Immunodeficiency Virus Protease Inhibitors on Neutrophil Apoptosis", <u>Journal of Infectious Diseases</u> (182), (November 2000), 1536-1539	✓
AS		MENG, LIHAO, et al., "Eponemycin Exerts Its Antitumor Effect through the Inhibition of Proteasome Function", <u>Cancer Research</u> , vol. 59, (June 15, 1999), 2798-2801	✓
AS		MENG, LIHAO, et al., "Epoxomicin, a potent and selective proteasome inhibitor, exhibits in vivo antiinflammatory activity", <u>Proc. National Academy of Science USA</u> , (August 1999), 10403-10408	✓
AS		MEYER, STEPHANIE, et al., "Cyclosporine A is an uncompetitive inhibitor of proteasome activity and prevents NF-kB activation", <u>Federation of European Biochemical Societies</u> , (1997), 354-358	✓
AS		MOSNAIM, ARON, et al., "Degradation Kinetics of Leucine5-Enkephalin by Plasma Samples from Healthy Controls and Various Patient Populations: In Vitro Drug Effects", <u>American Journal of Therapeutics</u> , vol. 7, (2000), 185-194	✓
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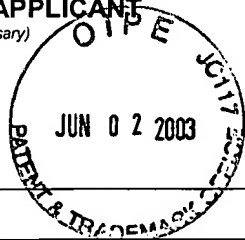
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		Apoptosis", <u>Cancer Epidemiology, Biomarkers &amp; Prevention</u> , vol. 10, (October 2001),1083-1088	
DS		NEPKA, CHARITINI, et al., "Chemopreventive activity of very low dose dietary tannic acid administration in hepatoma bearing C3H male mice", <u>Cancer Letters</u> , vol. 141, (1999),57-62	✓
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DS		PALOMBELLA, VITO, et al., "Role of the proteasome and NF-kB in streptococcal cell wall-induced polyarthritis", <u>Proc. National Academy of Science USA</u> , vol. 95, (December 1998),15671-15676	✓
DS		PETROV, VICTOR, et al., "Effect of Protease Inhibitors on Angiotensin-Converting Enzyme Activity in Human T-Lymphocytes", <u>American Journal of Hypertension</u> , vol. 13, no. 5, (May 2000),535-539	✓
DS		RAO, SHARMILA, et al., "Lovastatin-mediated G1 arrest is through inhibition of the proteasome, independent of hydroxymethyl glutaryl-CoA reductase", <u>Proc. National Academy of Science USA</u> , vol. 96, (July 1999),7797-7802	✓
DS		SCHWARTZ, DONALD, et al., "The neutral cysteine protease bleomycin hydrolase is essential for epidermal integrity and bleomycin resistance", <u>Proc. National Academy of Science USA</u> , vol. 96, (April 1999),4680-4685	✓
DS		SCHWARZ, KATRIN, et al., "The Selective Proteasome Inhibitors Lactacystin and Epoxomicin can be used to either Up- or Down-Regulate Antigen Presentation at Nontoxic Doses", <u>Journal of Immunology</u> , (2000),6147-6157	✓
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DS		SMITH, H., et al., "Effect of a cancer cachectic factor on protein synthesis/degradation in murine C2C12 myoblasts: modulation by eicosapentaenoic acid", <u>Cancer Res.</u> , 59(21), abstract,(November 1999),1 page	
DS		SON, KYONGHEE, et al., "Exposure of human ovarian carcinoma to cisplatin transiently sensitizes the tumor cells for liposome-mediated gene transfer", <u>Proc. National Academy of Science USA</u> , vol. 91, (December 1994),12669-12672	✓
DS		SON, K., et al., "Factors influencing the drug sensitization of human tumor cells for in situ lipofection", <u>Gene Therapy</u> (3), (1996),630-634	✓
DS		SON, KYONGHEE, et al., "Nitric oxide-mediated tumor cell killing of cisplatin-based interferon-γ gene therapy in murine ovarian carcinoma", <u>Cancer Gene Therapy</u> , vol. 7, no. 10, (2000),1324-1328	✓
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DS		TWEEDALE, TONY, "[Dioxin-I] Inhibits Estrogen-Induced Breast Cancer Cell	✓

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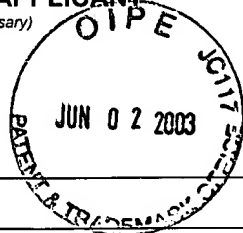
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PS		Proliferation", <u>Reuters Health</u> , <a href="http://lists.essential.org/pipermail/dioxin-I/Week-of-Mon-2000103/000096.html">http://lists.essential.org/pipermail/dioxin-I/Week-of-Mon-2000103/000096.html</a> , (December 1999), 1 page	
PS		WOESSNER, RICHARD , et al., "Comparison of Three Approaches to Doxorubicin Therapy: Free Doxorubicin, Liposomal Doxorubicin, and B- Glucuronidase-Activated Prodrug (HMR 1826)", <u>Anticancer Research</u> , (2000),2289-2296	✓
PS		WOJCIK, CEZARY , et al., "Lovastatin and simvastatin are modulators of the proteasome", <u>International Journal of Biochemistry &amp; Cell Biology</u> , (32), (2000),957-965	✓
PS		WORKING, PETER , et al., "Pharmacological-Toxicological Expert Report (Stealth Liposomal Doxorubicin HCl)", <u>Human &amp; Experimental Toxicology</u> , (1996),752-785	✓

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